K052825

Section H

JAN 20 2006

510(k) Summary for VisuLize™ Factor VIII Antigen Kit (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted By:

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Summary Prepared:

September 30, 2005

Name of the Device:

VisuLize™ Factor VIII Antigen Kit
Common Name: Factor VIII ELISA assay

Classification of Device:

Class II
21 CFR 864.7290, Factor Deficiency Test
Subpart H, Hematology Kits and Packages
Product Code: GGP

Predicate Device:

Coamatic® Factor VIII, K981038
Instrumentation Laboratory Co.

Device Description:

The VisuLize™ Factor VIII Antigen kit is a sandwich enzyme-linked immuno-sorbent assay (ELISA) using a polyclonal antibody coated 96-microwell format. Plasma samples are diluted and applied to the pre-coated wells. After washing away unbound proteins, a horseradish peroxidase (HRP) labelled polyclonal antibody is applied to detect the captured Factor VIII. A chromogenic substrate (TMB) is added to allow for color development. The color formed is measured spectrophotometrically at 450 nm, with the absorbance being directly proportional to the concentration of Factor VIII that was in the sample.

Device Intended Use:

The VisuLize™ Factor VIII Antigen Kit is an Enzyme Immunoassay for the quantitative determination of Factor VIII Antigen in human plasma samples and Factor VIII concentrates using the double antibody enzyme linked immuno-sorbent assay (ELISA).

Comparison to Predicate Device:

A technical comparison of the proposed device and the predicate device is illustrated in the following table:

	VisuLize™ Factor VIII Antigen Kit (Proposed Device)	Coamatic Factor VIII assay (Predicate Device)
Assay Principle	Quantitative determination (in IU/mL) of Factor VIII antigen by sandwich ELISA (polyclonal – polyclonal HRP)	Quantitative determination (in IU/mL) of Factor VIII activity by Factor Xa chromogenic activity assay.
Intended Use	An enzyme immunoassay for the quantitative determination of Factor VIII antigen in human plasma samples and Factor VIII concentrates using the double antibody enzyme linked immuno-sorbent assay (ELISA).	For the photometric determination of factor VIII activity in plasma such as when identifying factor VIII deficiency or monitoring patients on replacement therapy as well as for potency estimation of FVIII concentrates.
Technology	Double antibody enzyme linked immuno-sorbent assay (ELISA)	Chromogenic based assay
Sample Matrix	Human plasma derived from blood collected into 3.2% buffered citrate	Human plasma derived from blood (9 vol blood mixed with 1 vol 0.1mol/L citrate)
Intra-assay precision (CV%)	2.97 – 6.77% (mean results)	2.4 – 3.0%
Inter-assay precision (CV%)	3.38 – 6.66% (mean results)	2.1 – 5.9%
Linearity	Log-log curve, $R^2 \geq 0.990$	Linear curve
Detection Limit	0.008 IU/mL (0.8%)	Normal range: 0.05 IU/mL Low range: 0.005 IU/mL
Traceability of Calibrator Plasma	Calibrator plasma is standardized against a secondary standard that is traceable to the WHO International Standard for Factor VIII Antigen	Not provided with kit.

The technological difference between the 2 devices does not raise concerns regarding safety and effectiveness as the ELISA method is a well-characterized technology. Secondly, the performance evaluation carried out on the proposed device further supports its safety and effectiveness.

Clinical Performance Comparison:

The clinical performance of the VisuLize™ Factor VIII Antigen Kit versus the Coamatic® Factor VIII assay was compared to demonstrate substantial equivalence. Testing of clinical samples across the entire detection range was conducted internally and by two external testing sites. The results obtained by the three testing sites demonstrated excellent correlations between the proposed and predicate devices, as illustrated in the following table:

Summary of all Clinical Data from 3 Testing Sites

	INTERNAL TESTING	EXTERNAL TESTING SITE #1	EXTERNAL TESTING SITE #2
Number of Samples	142	100	81
Pearson Product Moment correlation co-efficient (r)	0.968	0.964	0.974

Conclusion: Based on the technical comparison and clinical performance results, it is concluded that the VisuLize™ Factor VIII Antigen kit is substantially equivalent to the Coamatic® Factor VIII assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 2 0 2006

Re: k052825
Trade/Device Name: VisuLize™ Factor VIII Antigen Kit
Regulation Number: 21 CFR§ 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: Class II
Product Code: GGP
Dated: December 5, 2005
Received: December 6, 2005

Dear: Ms. Foulon

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K052825

Device Name: VisuLize™ Factor VIII Antigen Kit

Indications for Use:

The VisuLize™ Factor VIII Antigen Kit is intended for use as an *in vitro* diagnostic assay for the quantitative determination of Factor VIII antigen in human plasma samples and Factor VIII concentrates using the double antibody enzyme linked immuno-sorbent assay (ELISA).

Prescription Use ✓ **AND/OR** Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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